510(k) Summary

JUN 14 2012

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Device Name

Trade Name	Vector^{4TM}
Common Name	Percutaneous Catheter
Classification Name	Percutaneous Catheter
Classification	II
Product Code	DQY, LIT

Predicate Device

The device is substantially equivalent to the Bard Conquest PTA catheter (K083657).

Indications for Use/Intended Use

The Vector$^{4\ TM}$ PTA Balloon Dilatation Catheter is recommended for Percutaneous Transluminal Angioplasty (PTA) of the femoral, iliac, popliteal, and renal arteries and for the treatment of obstructive lesions of native or synthetic arterio-venous dialysis fistulae.

The Vector Catheter is not indicated for use in the coronary arteries or for placement of or post dilatation of stents

Device Description and Technological Characteristics

The Vector^{4TM} PTA Catheter is a high pressure, non-compliant balloon catheter with a radiopaque coating on the balloon. The radio-opaque coating on the working length of the balloon

minimizes or eliminates the need for using contrast solution to inflate the balloon. The radio-opaque coating delineates the working length of the balloon and provides continuous fluoroscopic visibility during balloon placement. Saline may be used to inflate the balloon without affecting visualization. Contrast mixture may be used at the discretion of the physician.

The Vector^{4TM} PTA Balloon Dilatation Catheter is a coaxial dual lumen over-the-wire balloon dilatation catheter. The central lumen accommodates guide wires up to 0.035 inches in diameter while the outer lumen is the inflation lumen for the balloon. The catheter includes an atraumatic tip to ease advancement of the catheter to and through the stenosis. The distal tip is visible under fluoroscopy.

The balloon is a high pressure composite balloon with a radiopaque coating on the working length to help visualize placement within the lesion during both placement and inflation without the use of contrast. The balloon's rated burst pressure is 30 atm.

The catheter is supplied sterile and non-pyrogenic. Different balloon sizes (5 mm to 10 mm) and catheter lengths (50 to 135 cm) are available. The proximal end of the catheter contains a hub with two female luer locks.

The device is compatible with 6-7F introducers. The introducer compatibility for each device size is listed on the device label itself. The materials used in the construction are biocompatible and latex free.

Performance Data

The Vector^{4TM} PTA Balloon Dilatation Catheter is tested and meets all its physical and performance specifications including:

- Balloon rated burst pressure
- Balloon compliance
- Critical dimension verifications
- Guidewire and introducer compatibility
- Fluoroscopic visualization
- Inflation/deflation times
- Repeat inflation
- Leak
- Tensile
- Kink
- Torque
- Corrosion
- Luer lock compatibility
- Coating integrity
- Distribution

In addition, the device was tested for biocompatibility ISO 10993-1 for short duration contact with blood (<24 hour).

The device is sterilized by ethylene oxide to an SAL 10^{-6} level. These performances are similar to that described by the predicate device as these are standard tests for PTA catheters. In addition, direct comparative testing for radiopacity and particulates was conducted for both devices and results found to be similar.

After accelerated aging on devices, a subset of the original tests that may be affected by aging were repeated.

The preclinical testing showed that the device meets specifications before and after aging indicating that the device is as safe and effective as the predicate device.

Substantial Equivalence

The Vector$^{4™}$ is substantially equivalent to the Conquest PTA catheter (K083657). They have similar intended use, and treat the same target population. Both devices are intended to treat peripheral arteries. The Vector$^{4™}$ is indicated for an additional artery - popliteal artery which is also a peripheral artery with similar sizes and access as the other peripheral arteries. The manner in accessing and treating lesions in all these arteries is similar. Therefore, this minor change in indication for use does not change the intended use of the device and does not raise new safety and effectiveness question.

Both devices employ a composite balloon construction to attain the high rated burst pressures. Both devices are over the wire catheters with coaxial lumens. Both devices are compatible with 0.035" wires and have similar construction and principles of operation. Both devices are used by the physician in a similar manner typical of all PTA balloon catheters. Both devices are sterilized with ethylene oxide with a sterility assurance of 10^{-6}.

Fluoroscopic visualization for the Conquest balloon is achieved by injecting contrast into the balloon of the Conquest catheter while the radiopaque coating on the Vector balloon allows visualization without contrast. This difference does not raise new safety and effectiveness questions as the visualization under fluoroscopy has been shown to be equivalent for both devices.

Conclusion

The non-clinical testing of the Vector$^{4™}$ PTA Balloon Dilatation Catheter met all the product specifications, and all the required standards for sterility and biocompatibility. The Vector$^{4™}$ and the predicate Conquest PTA catheters have similar intended use and technological characteristics and are therefore substantially equivalent. These tests showed that the Vector$^{4™}$ PTA Balloon Dilatation Catheter is as safe and effective as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN 14 2012

r4 Vascular, Inc.
c/o Mark Job
Responsible Third Party Official
Regulatory Technical Services LLC
1394 25th Street NW
Buffalo, MN 55313

Re: K121385
Trade/Device Name: Vector[4] PTA Balloon Dilatation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II (Two)
Product Code: LIT, DQY
Dated: May 7, 2012
Received: May 8, 2012

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use Statement

Indications for Use

510(k) Number (if known): K121385

Device Name: Vector4™ PTA Catheter

Indications for Use:
The Vector^{4} ™ PTA Balloon Dilatation Catheter is recommended for Percutaneous Transluminal Angioplasty (PTA) of the femoral, iliac, popliteal, and renal arteries and for the treatment of obstructive lesions of native or synthetic arterio-venous dialysis fistulae.

The Vector Catheter is not indicated for use in the coronary arteries or for placement of or post dilatation of stents

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___ ____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K121385